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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 10/633,023 | 07/31/2003 | H. Ernest Schnepp | MA-20CCCD4 | 5003 |
| 23557 | 7590 | 04/04/2006 | EXAMINER | |
| SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950 | | | BUGAISKY, GABRIELE E | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1656 | | |

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/633,023 | SCHNEPF ET AL. | |
| | Examiner | Art Unit | |
| | Gabriele E. BUGAISKY | 1656 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 March 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,26 and 27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/31/03, 11/3/03.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of the δ -endotoxin of *Bt strain PS52A1* (the protein of SEQ ID NO:8, encoded by SEQ ID NO:7) in the papers filed 3/21/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

All non-elected claims have been cancelled.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specific wash conditions of the claim appear to have no support in the specification. The Examiner has carefully reviewed the sections of the specification which were indicated as providing support for the amended claims & can find no mention of these conditions. At best, there is a citation of the Maniatis cloning manual, but no pages are indicated. Applicants have submitted two specific pages of that text, but the reference has not been made of record. Further, one might conjecture an improper incorporation by reference; however, these pages are directed to screening of bacterial colonies or bacteriophage plaques.

Claims 1 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nematicidal proteins encoded by SEQ ID NO:7, does not reasonably provide enablement for nematicidal proteins encoded by polynucleotides whose complement remains hybridized under the recited conditions to SEQ ID NO:7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.. Applicants have obtained the specific protein of SEQ ID NO:8 but provided no teaching where one may reasonably expect to find other such proteins encompassed by the claims. The specification does not provide for the specific recited conditions. One has been given an invitation to experiment to try to find homologues of SEQ ID NO:8.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1-2, 26 and 27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6632792. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are directed to a toxin comprising SEQ ID NO:8 and a method of nematode control with the toxin; SEQ ID NO:8 is encoded by instant SEQ ID NO:7. Thus, the claims are directed to the same toxin.

Claims 1-2, 26 and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 29-30, and 41-43 of U.S. Patent No. 4849217. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a specific δ -endotoxin encoded by SEQ ID NO:7 from PS-52A1, and a method of its use in killing nematodes, whereas the claims of the patent are directed to compositions selected from a group of cell lines, spores, toxins, and

crystals from a large number of recited cell isolates including PS-52A1 , and their use in a method of controlling insect infestations of alfalfa. The patent also recites claims to toxins active against the Egyptian alfalfa weevil produced by a large number of cell lines including PS-52A1.

Absent evidence to the contrary, a method of controlling insect infestations of alfalfa is presumed to be unpatentable from a method of controlling nematodes, since the treatment method does not appear to be distinct (in the patented treatment method, it is presumed that nematodes in an alfalfa field would be controlled by the application method for alfalfa infestations) . Likewise, with respect to the specific protein encoded by SEQ ID NO:7, it is presumed to be identical to the one claimed in the patent.

Claims 1-2, 26 and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 10, 13-14, 17, and 20 of U.S. Patent No. 4948734. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are directed to a process of controlling nematodes using an effective amount of a toxin produced by a *B.t* isolate, from a list of strains including pS-52A1. Absent evidence to the contrary, the patented process of controlling nematodes relies on the specific instant protein of SEQ ID NO:8, which is encoded by SEQ ID NO:7. The specific nematicidal toxin is deemed patentably indistinguishable from its use to control nematodes- the purified toxin is deemed obvious from its manner of use to control nematodes.

Claims 1-2, 26 and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5093120. Although the conflicting claims are not identical, they are not patentably distinct from each other

because the claims of the patent are directed to a process of controlling nematodes using an effective amount of a toxin produced by a *B.t* isolate, from a list of strains including pS-52A1 .

Absent evidence to the contrary, the patented process of controlling nematodes relies on the specific instant protein of SEQ ID NO:8, which is encoded by SEQ ID NO:7. The specific nematicidal toxin is deemed patentably indistinguishable from its use to control nematodes- the purified toxin is deemed obvious from its manner of use to control nematodes.

Claims 1-2, 26 and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5322932. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the patent is to a isolated toxin active against nematodes, which is encoded by a DNA sequence found in NM522 (pMYC2321). This DNA sequence encodes SEQ ID NO:8, and thus the claims are deemed patentably indistinguishable because the toxins are the same, even though the wording of the claims is not identical. A method of controlling nematodes using a nematicidal toxin is deemed an obvious use of the toxin..

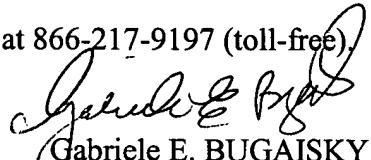
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (571) 272-0945. The examiner can normally be reached on Tues.- Fri 8:15 AM-1:45 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1656